

## Amendments affecting export of medicines from Bulgaria

The Bulgarian Parliament adopted amendments to the Medicinal Products in Human Medicine Act (MPHMA) in October 2018. The amendments claimed to be in favour of the safety of Bulgarian patients if there is a shortage of particular medicines that can protect the life and health of the population. According to certain market statistics, the parallel export of medicines in Bulgaria for 2017 amounted to 8% of the medicinal products market. The fact that the prices of medicines on that market are lower in comparison to other EU countries stimulates parallel export.

The new rules are aimed at introducing a specialized electronic system for tracking and analysis of the medicinal products included in what is known as the Positive Drugs List. The Positive Drug List includes medicinal products subject to medical prescription and paid for from the National Health Insurance Fund (NHIF), the state budget, and from the budget of individual hospitals. The specialized electronic system will contain information provided by the marketing authorization holders, the holders of a licence to wholesale and retail of medicinal products and holders of a parallel import licence. This information will be comprised of data for the Positive Drugs List medicines which have been distributed as well as for those available in the stocks of the relevant entities. Additional information regarding the Positive Drug List medicines will be provided by the NHIF and the Ministry of Health.

This input information will be used for the purposes of analysing and identifying situations of shortage of particular medicines for Bulgarian patients. A situation of shortage is considered to be when the quantities of a particular medicine available on the territory of Bulgaria are less than 65% of the quantities necessary to meet the needs of the population for a period of one month. The necessary quantities are to be calculated on the basis of the average monthly consumption of the relevant medicine for the past six months.

A special list for medicinal products subject to shortage is to be prepared. These medicinal products cannot be exported while they are on the list. The list will be publicly available on the Bulgarian Drug Agency website and it shall be updated weekly or if there is any change in the circumstances related to the export/import of medicines included in the Positive Drug List.

Infringements of the above rules will be sanctioned with a fine of between €2,500 and €75,000 depending on the particular infringement. Wholesalers might be sanctioned with the loss of their licences.

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